

AUG 29 2006

REMARKS

The above Amendments and these Remarks are in reply to the Office Action mailed July 31, 2006. Claims 1-71 were pending in the Application prior to the outstanding Office Action. Claims 1, 19, 37 and 47 are being amended. The amendments to Claims 1, 19, 37 and 47 are supported by the limitation of Claims 1 and 62, and are therefore supported by the present disclosure. Claims 68-71 are withdrawn. Claims 1-67 remain for the Examiner's consideration. Reconsideration and withdrawal of the rejections are respectfully requested.

CLAIM REJECTIONS UNDER 35 U.S.C. § 103

A) Claims 1 and 19

Claims 1, 3-4, 6-10, 12, 14-20, 23, 26-27, 29-31 and 33-36 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Zucherman et al. (U.S. Patent No. 6,048,342), hereinafter '342, in view of Brantigan (U.S. Patent No. 4, 834,757), hereinafter '757.

The Examiner states that '757 teaches the incorporation of radiolucent material for improved X-ray visualization of the device.

The limitations of amended Claims 1 and 19 require that the "shaft is made of radiopaque material" and the "tissue expander is at least in part radiolucent" (Claim 19 has an additional limitation that the "spacer is at least in part radiolucent"). Thus these limitations require that the implant is partially radiopaque and partially radiolucent. The '757 specification refers to radiolucent in the introduction (as cited by the Examiner) and in the summary of the invention, where it is stated "the blocks or plugs can be made

of a radiolucent material ...". Column 3, line 65-67. However, '757 is silent with regard to a portion or part of the implant being radiolucent.

The Applicant has amended Claims 37 and 47 including the limitation that the shaft is radiopaque. Since '342 and '757 are silent as to an implant containing both a radiolucent tissue expander and a radiopaque shaft the references cited do not teach or suggest all the limitations of Claims 1, 19, 37 and 47.

B) Claims 3-4, 6-10, 12, 14-18, 20, 23, 26-27, 29-31 and 33-36

Claims 3-4, 6-10, 12, 14-18, 20, 23, 26-27, 29-31 and 33-36 all directly or indirectly depend from independent Claims 1 and 19, and are therefore believed patentable for at least the same reasons as the independent Claims 1 and 19, and because of the additional limitations of these claims.

C) Claims 2, 13 and 21-22

Claims 2, 13 and 21-22 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the combination of '342 and '757 as applied to Claims 1 and 19, respectively, and further in view of Brantigan (U.S. Patent No. 5,192,327), hereinafter '327.

Claims 2, 13 and 21-22 all directly or indirectly depend from independent Claims 1 and 19, and are therefore believed patentable for at least the same reasons as the independent Claims 1 and 19, and because of the additional limitations of these claims.

D) Claims 11 and 24-25

Claims 11 and 24-25 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the combination of '342 and '757 as applied to Claims 1 and 19, respectively, and further in view of Branch (U.S. Publication No. 2002/0016592) hereinafter '592.

The Examiner states that '592 discloses a fusion device that is at least partially radiopaque that allows a means for viewing placement of the implant via radiography during surgery.

The Applicant respectfully disagrees with the Examiners characterization of '592. The word 'radiopaque' appears in the specification of '592, at paragraphs [0009], [0135] and [0166]. The '592 application teaches an impact holder where a "gripping head includes at least one implant engaging structural feature, such as a pin". 4th sentence, paragraph [009]. Fig 23 shows the impact holder and Fig 23a shows the end of the impact holder with the engaging structural feature or pin 246. Paragraph [025] discloses an embodiment of the implant engaging structure, where "[g]ripping head 244 also includes first rod extension 246. First rod extension 246 can include external threads for engaging internal threads in a tool receiving recess in an implant. Preferably rod extension 246 is radiopaque to provide an X-ray *indicator* of the location of the implant *during surgery*" (emphasis added). It is not the implant that is radiopaque but rather the tool. Further, it is understood that the radiopaque first rod extension is fixed on the impact holder and is only received in the implant during surgery, "[e]xtension rod 246 can extend through an aperture on surface 244 to be received within shaft". Thus the radiopaque material is part of the impact holder not the implant. Another embodiment of

the implant engaging structure is shown in Fig 40b. According to paragraph [0166], “.... shaft extension 599 is radiopaque and extends through the implant body to or through the insertion end. Radiopaque shaft extension 599 provides a means for viewing the seating of an implant *during surgery* via radiography.” (emphasis added).

Accordingly, the embodiments described in ‘592 disclose a radiopaque pin which is a part of a tool, but not the implant. As a consequence, the radiopaque part is an indicator only during surgery, since the tool with the radiopaque part is removed from the patient with the tool upon completion of the surgery and sealing of the wound. In contrast, the limitation of amended Claims 1 and 19 require that the “tissue expander is at least in part radiolucent”. This is a requirement that a part of the implant, not a tool to insert the implant is radiolucent. This results in a significant practical utility, since the contrast of an implant made up of partial radiolucent materials can be detected at any time during surgery or *after surgery*. Therefore, the references cited do not teach or disclose all the limitations of Claims 1 and 19.

Claims 11 and 24-25 all directly or indirectly depend from independent Claims 1 and 19, and are therefore believed patentable for at least the same reasons as the independent Claims 1 and 19, and because of the additional limitations of these claims.

E) Claims 5 and 28

Claims 5 and 28 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the combination of ‘342 and ‘757 as applied to Claims 1 and 19, respectively, and further in view of Zucherman (U.S. Publication No. 2001/0012938) hereinafter ‘938.

Claims 5 and 28 both directly depend from independent Claims 1 and 19, and are therefore believed patentable for at least the same reasons as the independent Claims 1 and 19, and because of the additional limitations of these claims.

F) Claims 37 and 47

Claims 37, 39-41, 43-46, 49, 47-48, 50, 53-55 and 57-61 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over '342 in view of and '327.

Amended Claims 37 and 47 recite "a body including a shaft; wherein the shaft is radiopaque" and "a tissue expander extending from the shaft is at least in part radiolucent". As such the '342 and '327 references do not teach or disclose these limitations of amended Claims 37 and 47.

G) Claims 39-41, 43-46, 49, 48, 50, 53-55 and 57-61

Claims 39-41, 43-46, 49, 48, 50, 53-55 and 57-61 all directly or indirectly depend from independent claims 37 and 47, and are therefore believed patentable for at least the same reasons as the independent Claims 37 and 47, and because of the additional limitations of these claims.

H) Claims 38 and 51-52

Claims 38 and 51-52 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the combination of '342 and '327 as applied to Claims 37 and 47, respectively, and further in view of '592.

'592 teaches a radiopaque part associated with a tool not an implant. As a consequence, the radiopaque part is an indicator only during surgery, since the tool with the radiopaque part is removed from the patient with the tool. Claims 38 and 51-52 recite the limitation "... radiopaque such that under imaging the implant resembles an H-shape". There is no reference in the claim to limit the imaging to only *during surgery*. The Examiner is impermissibly construing a limitation on the claim in light of the '592 teaching. In fact the Applicants invention, because it is partially radiopaque, could be imaged at any time during and/or after surgery. Thus, '342, '327 and '527 do not teach all limitations of Claims 38 and 51-52.

D) Claims 42 and 56

Claims 42 and 56 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the combination of '342 and '327 as applied to Claims 37 and 47, respectively, and further in view of '938.

Claims 42 and 56 both directly depend from independent Claims 37 and 47, and are therefore believed patentable for at least the same reasons as the independent Claims 37 and 47, and because of the additional limitations of these claims.

J) Claim 62

Claims 62, 64-65 and 67 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over '342 in view of the combination of '757 and '592.

'757 is silent with regard to a portion or part of the implant being radiolucent. '592 teaches a radiopaque part associated with a tool not an implant. There is no

teaching or suggestion to use radiolucent materials for only a part of the implant. Nor is there a teaching or suggestion to use radiopaque materials for only a part of the implant. As such, the '342, '757 or '592 do not teach or disclose all the limitations of Claim 62.

K) Claims 64-65 and 67

Claims 64-65 and 67 all directly depend from independent Claim 62, and are therefore believed patentable for at least the same reasons as the independent Claim 62, and because of the additional limitations of these claims.

L) Claims 63 and 66

Claims 63 and 66 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the combination of '342, '592 and '757, as applied to Claims 62 and 64, respectively, and further in view of '327.

Claims 63 and 66 both directly or indirectly depend from independent Claim 62, and are therefore believed patentable for at least the same reasons as the independent Claim 62, and because of the additional limitations of these claims.

In view of the above, Applicants respectfully request that the Examiner reconsider and withdraw the 103(a) rejections.

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CONCLUSION

In light of the above, it is respectfully requested that all outstanding rejections be reconsidered and withdrawn. The Examiner is respectfully requested to telephone the undersigned if he can assist in any way in expediting issuance of a patent.

No fee is believed due in connection with this Reply. However, the Commissioner is authorized to charge any underpayment or credit any overpayment to Deposit Account No. 06-1325 for any matter in connection with this reply, including any fee for extension of time, which may be required.

Date: _____

8/29/06

By: _____

Respectfully submitted,

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